IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of Embil *et al.*	: Group Art Unit 1615
Serial No.: 10/761,390	: Examiner Channavajjala
For: Topical Pharmaceutical and/or Cosmetic Dispense Systems	:
Filed: January 22, 2002	:

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Declaration of Sergio Nacht, Ph.D. Under 37 C.F.R. § 1.132

I, Sergio Nacht, being duly sworn depose and say:

1. I am a co-inventor of the invention claimed in the above-referenced application (the "Embil/Nacht Application"). I have prepared this Declaration for consideration by the US Patent and Trademark Office in connection with the Response to the Final Office Action being filed on April 2, 2009.

2. I received my Ph.D. in biological chemistry in Argentina. In 1964, I immigrated to the United States to become a Assistant Research Professor in Medicine at the University of Utah.

3. Beginning in 1970, when I joined Alza Corporation (Palo Alto, California), and continuing to date I have over thirty-five years of commercial experience with innovative raw materials and finished goods companies in the skincare industry, including cosmetic and dermatological products.

4. At Alza, I was responsible for skin permeability and biological studies of transdermal delivery systems. For the next 14 years, I was Director of Biomedical Research for the Personal Care Division of Richardson-Vicks, Inc. / Procter & Gamble. In that capacity, I conducted and directed laboratory and clinical research on the

physiology and function of human skin and hair. In addition at Vicks/P&G, I was responsible for the safety, efficacy and claim substantiation of skin and hair products, including Clearasil, Oil of Olay and Pantene. During this time, I was also a lecturer in the Department of Medicine, Dermatology Division, State University of New York, Downstate Medical Center.

5. After working at Vicks/P&G, I became Senior Vice President of Research and Development at Advanced Polymer Systems, Inc. Thereafter, I was Senior Vice President of Dermatology and Skin Care at Cardinal Health, Topical Technologies. I am presently Co-Founder and Chief Scientific Officer of Riley-Nacht, LLC, a global skincare technology firm that I co-founded in 2002. Riley-Nacht identifies, develops and represents innovative technologies, including active ingredients and delivery systems.

6. I am a member of several professional societies, including the American Academy of Dermatology, the Society for Investigative Dermatology and the Society of Cosmetic Chemists. I have co-authored more than 50 scientific papers and book chapters and am co-inventor on fourteen US patents.

7. In connection with this Declaration, I have reviewed the Final Office Action issued by the USPTO on October 2, 2008 and the prior art references cited therein, including International Patent Application WO 93/15726 to Baroody *et al* ("WO26") and European Patent Application EP 306236 to Katz *et al.*

8. The formulations taught in WO26 do not have lipophilic components and are not emulsions as claimed in the Embil/Nacht Application.

9. In order for the dispense means of the present invention to work as claimed in the Embil/Nacht Application (*i.e.*, to permit dispense of a first emulsion formulation in a specific ratio to a second emulsion formulation), the viscosities of the two formulations must be matched to within a certain percentage of each other – varying by no more than 10%, preferably by no more than 5%, and still more preferably by no more than 2.5%.

10. Additionally, in order for the dispense means of the Embil/Nacht Application to work in the claimed manner, the formulations must have viscosities of less than about

25,000 cps, preferably less than about 20,000 cps, and more preferably less than about 10,000 cps.

11. The emulsion formulations having substantially the same viscosity as claimed in the Embil/Nacht Application utilize polymers capable of entrapping and controlling the release of at least one active ingredient. Carboxy vinyl polymer as taught in WO26 is a swellable polymer – specifically a gelling agent – and is not a polymeric delivery system of the type claimed in the Embil/Nacht Application.

12. EP 306236 describes a porous solid particle polymeric delivery system in which the pores form a continuous network open to the exterior of the particles, permitting the outward diffusion of the impregnant at a controlled rate. Clindamycin is a water-soluble, hydrophilic ingredient. Impregnating clindamycin (or another hydrophilic ingredient) into this type of porous solid particle polymeric delivery system and then adding the resulting "loaded" delivery system into the aqueous formulations taught in WO26 would result in "dose dumping." The rate of delivery of the clindamycin would not be controlled in the aqueous formulations taught in WO26. Put differently, impregnating clindamycin into the delivery system described in EP 306236 would defeat the purpose of having a controlled release formulation.

13. Benzoyl peroxide ("BPO") is a lipophilic active ingredient. Since the aqueous formulations taught in WO26 do not have lipophilic components, a delivery system as described in EP 306236 loaded with BPO would not deliver the lipophilic active ingredient (*i.e.*, BPO) in the formulations taught in WO26.

Further Declarant says not.

The foregoing statements are made of my own knowledge and are true. I have been warned that willful false statements and the like are punishable by fine or imprisonment, or both, and that such statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: April 1, 2009

Sergio Nacht, Ph.D.